Atty. Dkt. No. 087147-0437

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Tamura Norikazu et al.

Title: PHARMACEUTICAL COMPOSITION

Appl. No.: 09/551,546

Filing Date: April 18, 2000

Examiner: R. Travers

Art Unit: 1617

RESPONSE TO RESTRICTION REQUIREMENT UNDER 37 C.F.R. 1.143

Commissioner for Patents
Box NON-FEE AMENDMENT
Washington, D.C. 20231

Sir:

In response to the restriction requirement set forth in the Office Action mailed June 27, 2001, Applicants hereby elect Group I (claims 20 and 28-33), with traverse. This election of claims is made without prejudice to Applicants' right to pursue the non-elected claims in one or more divisional applications in due course. The deadline for response to this restriction requirement has been extended for one month, to August 27, 2001, by filing a Petition for Extension of Time and payment of the appropriate fee under 37 C.F.R. §§ 1.136 and 1.17(a)(2).

The Commissioner may require restriction if two or more independent and distinct inventions are claimed in one application (35 U.S.C. §121). In the present case, the inventions are not independent, thus restriction is improper.

The Examiner classified the claims into three groups. According to the Examiner, Group I (claims 20 and 28-33) is drawn to methods of treating angiotensin II mediated diseases by administering an angiotensin II antagonistic compound concomitantly with a compound possessing anti-hyperglycemic, angiotensin coverting enzyme inhibitory, or HMG-Co A inhibitory activity. The Examiner also asserts that Group II (claims 23 and 34-36) is drawn to a method for treating various maladies by administering an angiotensin II

antagonistic compound concomitantly with a compound possessing anti-hyperglycemic, angiotensin converting enzyme inhibitory, or HMG-Co A inhibitory activity; and Group III (claims 22 and 24-26) is drawn to a method for treating circulatory diseases by administering an angiotensin II antagonistic compound concomitantly with a compound possessing anti-hyperglycemic, angiotensin converting enzyme inhibitory, or HMG-Co A inhibitory activity.

The Examiner then alleges that the methods in Groups I, II and III are directed to "methods for treating various diseases employing a plurality of patentably distinct species." Applicants respectfully traverse this restriction.

In making the assertion that more than one invention exists, the Examiner relies on PCT Rule 13.1 in applying the "unity of invention" standard. In view of PCT Rule 13.1, Applicant respectfully disagrees with the Examiner that more than one invention exists in the current application, and asserts that all of the claims in the current invention share the same special technical feature as outlined in PCT Rule 13.1. Further, the PCT Administrative Instructions (Annex B, Part I, (c)(i)) state that "If the independent claims avoid the prior art and satisfy the requirement of unity of invention, *no problem of lack of unity arises in respect of any claims that depend on the independent claims*. In particular, *it does not matter if a dependent claim itself contains a further invention*." (emphasis added).

Thus, if all independent claims of the current invention avoid the prior art, then all claims dependent upon these independent claims will possess unity of invention and must be examined in concert. In the current context, all dependent claims of the current application have in common the feature of treating an angiotensin II-mediated disease in a mammal, comprising administering an angiotensin II antagonist in combination with another compound, which is a special technical feature, among several, of the present invention that unify all the claims of the current application. Further, the examiner has presented no evidence that the independent claims do not avoid the prior art. Accordingly, all claims of the current application should be examined together.

In addition, to establish a proper requirement for restriction, the Examiner must demonstrate that the independent and distinct inventions meet two criteria. First, the